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environmental restoration project

A Department of Energy Environmental Cleanup Program

Environmental Restoration Project
Quality Procedure

for:

Control of Measuring and Test Equipment

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Revision Log

Revision No.	*Effective Date*	*Prepared By*	*Description of Changes*	*Affected Pages*
R0	07/20/01	Andrew E. Gallegos	New Procedure	All
Reviewed	04/29/2004	Phil Noll	Deemed adequate.	

Control of Measuring and Test Equipment

Table of Contents

Control of Measuring and Test Equipment

1.0 PURPOSE

This Quality Procedure (QP) states the responsibilities and describes the process for identifying, maintaining, and managing Measuring and Test Equipment (M&TE) within the Environmental Restoration (ER) Project.

Note: This procedure does not provide instructions on how to calibrate M&TE. For those instructions, the M&TE custodian must refer to United States national standards maintained by the National Institute of Standards and Technology (NIST), national standards of other countries that are correlated with US national standards, accepted values of fundamental physical constants, values derived by the ratio type of self-calibration techniques, values obtained using nationally accepted measurement systems, comparison with consensus standards, manufacture instructions, calibration laboratory procedures and/or other approved instructions.

2.0 SCOPE

This QP is a mandatory document and shall be implemented by all ER Project participants when calibrating and controlling M&TE for the ER Project.

Note: Subcontractors may follow this QP for the control of measuring and test equipment (M&TE) or may use their own procedures as long as those procedures meet the requirements prescribed by the ER Project Quality Management Plan, Quality, and is approved by the ER Project's Quality Program Project Leader (QPPL) before the commencement of the procurement activities.

3.0 REFERENCES

ER Project personnel should become familiar with the contents of the following documents to properly implement this QP.

- ER Project Quality Management Plan located at http://erinternal.lanl.gov/home_links/Library_proc.htm.
- QP-2.2, Personnel Orientation and Training
- QP-3.2, Lessons Learned
- QP-3.4, Managing Nonconformances, Deficiencies, and Corrective Actions
- QP-4.4, Record Transmittal to the Records Processing Facility

- QP-5.7, Notebook Documentation for Environmental Restoration Technical Activities
- QP-7.1, Procurement
- QP-7.2, Supplier Evaluation
- ANSI/NCSL Z540-1-1994, American National Standards for Calibration

4.0 DEFINITIONS

4.1 *Accuracy* — The degree of agreement of the measurement with the true value of the quantity measured.

4.2 *Calibration* — The comparison of measuring and test equipment to a measurement standard of known accuracy. Calibration is performed in order to establish the suitability of M&TE to perform an intended measurement task.

4.3 *Calibration Standard* — A reference used in measurement or test comparisons with working M&TE.

4.4 *Certification* — A calibration performed by a Standards and Calibration Laboratory (i.e., LANL ESA-MT or the Radiation Instrumentation and Calibration Laboratory in ESH-4).

4.5 *Consensus Standard* — An artifact or process that is used as a de facto standard when no recognized U.S. national standard is available.

4.6 *Consumable Calibration Standard* — A standard that may be used up over a period of time.

4.7 *M&TE Custodian* — All inclusive term that identifies a person responsible for ensuring that a unit of M&TE is maintained and calibrated or a standard is documented and maintained.

4.8 *Measuring Assurance Program* — A quality control program for continuously calibrating an entire measurement system, in which a calibrated artifact is periodically measured by the system and the results are used to estimate random error and ensure that the measurement process remains in a state of statistical control.

4.9 *Measuring and Test Equipment* — Devices or systems used to calibrate, measure, gauge, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

4.10 *National Institute of Standards and Technology (NIST)* — The highest level metrology organization in the United States. The NIST serves as the source of traceability for most measurements in this country.

4.11 *Operational Check* — An examination performed and documented to verify that M&TE is functioning and operating with in specified tolerance.

4.12 *Out of Calibration* — All inclusive term that identifies M&TE which has never been calibrated, has not been recalibrated within the required time period, has been subjected to recalibration procedures or periodic checks and found to be out of the allowed specification tolerances (i.e., out of tolerance), or has been damaged or found in condition that has been determined to be suspect.

4.13 *Precision* — A quantitative measure of the variability of a set of repeated measurements.

4.14 *Tolerance* — That range of values within which it has been calculated that a specified percentage of individual values of measurements will lie with a stated confidence level.

4.15 *Tolerance limits* — The extreme values (upper and lower) that are permitted by the tolerance.

4.16 *Unique identifier* — A tracking number assigned by the M&TE database custodian.

4.17 *Verification* — A calibration performed by the user, the M&TE manufacture, or a calibrator other then the Standards and Calibration Laboratory.

5.0 RESPONSIBLE PERSONNEL

The following personnel are responsible for activities identified in Section 6.0 of this procedure.

5.1 Calibrator

5.2 ER Project Personnel

5.3 M&TE custodian — A Focus Area or team member assigned responsibility for maintaining M&TE.

5.4 M&TE database coordinator — An ER Project Liaison assigned responsibility for maintaining the ER Project M&TE database.

5.5 M&TE user

5.6 Supervisor

6.0 PROCEDURE

Note: ER Project personnel may produce paper copies of this procedure printed from the controlled-document electronic file located at http://erinternal.lanl.gov/home_links/Library_proc.htm. However, it is their

responsibility to ensure that they are trained to and utilizing the current version of this procedure. The QPPL may be contacted if text is unclear.

6.1 M&TE Management

Note: Refer to the Los Alamos National Laboratory (LANL) Calibration Program located at http://www.esa-mt.lanl.gov/s&cl/calprog.htm for specific guidance in controlling M&TE at LANL.

Note: The instructions in this section shall be followed each time M&TE calibration is found to be in question and/or the M&TE is being calibrated.

The **M&TE custodian** completes Section 1 of the M&TE Report (Attachment A) with special emphasis as follows.

6.1.1 Ensures that the identifier for M&TE in item 1 is unique (e.g., serial number, property number or a sequential tracking number assigned from the M&TE database);

Note: Every item that is periodically calibrated, regardless of the calibrator, must be uniquely identified using its serial number, an optional file number assigned by a Standards and Calibration Laboratory, or other unique identification. Items that are calibrated at the time of each use must also be assigned a unique identification

6.1.2 Defines in item 6 the method and interval of calibration for each device based on the type of equipment, stability characteristics, required accuracy, intended use, and other applicable conditions which may affect measurement control;

6.1.3 Documents in item 7 any special storage and handling requirements that are necessary to maintain accuracy of the device;

6.1.4 For M&TE calibrated at each use, enters “at each use” in item 6 and enters “n/a” with initial and date on lines 19 and 21 to document that these sections are not applicable;

6.1.5 Ensures that standards are traceable to nationally recognized standards (see Section 1.0 note) and enters “N/A” in item 9. (if a physical constant does not exist, documents the basis for calibration in item 9);

6.1.6 If the calibration standards have a higher accuracy than the M&TE being calibrated, enters “n/a” in item 10;

Note: The calibration standard used should have accuracy at least four times greater than the device under test.

6.1.7 If standards with an accuracy equal to the M&TE being calibrated must be used and can be shown to be adequate for the requirements, documents the basis for calibration acceptance in item 10; and

6.1.8 Signs and dates the signature block on line 11 for initial entries or for subsequent changes to the information in Section I.

6.2 Calibrate M&TE at a Set Frequency

6.2.1 The **M&TE custodian** initiates a purchase request, in accordance with QP-7.1, Procurement, if the calibration is to be performed by an agency outside the Laboratory;

6.2.2 The **M&TE custodian** contacts an approved Laboratory Standards and Calibration organization if the calibration is to be performed by the ER Project;

Note: Following guidance in QP-7.2, Supplier Evaluation to determine if the approved laboratory has been placed in the ER Project “Approved Supplier’s List”.

6.2.3 The **M&TE custodian** verifies that the calibration is performed and that the calibrator completes Section II of the M&TE Report (Attachment A);

Note: This information may be supplied on the M&TE Report or on separate documentation that is traceable to the M&TE Report.

6.2.4 The **M&TE custodian** completes Section III of the M&TE Report, as applicable, and signs and dates item 21;

6.2.5 The **M&TE custodian** performs the activities stated in Section 6.4 of this QP if the M&TE accuracy was out of tolerance during calibration or if the M&TE could not be calibrated;

6.2.6 The **M&TE custodian** verifies that a required calibration label (see Attachment C) is placed on or adjacent to the M&TE.

6.2.7 The required labels are those necessary to indicate the status of periodically calibrated items. In this system, the word "certification" designates calibrations performed by a Standards and Calibration Laboratory; "verification" refers to calibrations performed by the user or other calibrators. When a calibrator outside the ER Project supplies a label that contains the M&TE file number and its calibration and expiration dates, this label is acceptable as a substitute for a required label.

6.2.8 The optional labels (see Attachment D) indicate the status of M&TE that

- are calibrated at the time of use,
- do not require calibration,
- are inactive, or

- have expired calibrations.

6.2.9 In some cases, these optional labels may help employees determine the proper status of M&TE, but their use is entirely at the discretion of each division.

Note: Calibration labels can be obtained from the LANL ESA-MT.

6.2.10 The **M&TE custodian** verifies that the M&TE Report is complete and that all items contain the applicable information, or that the information is attached.

6.2.11 The **M&TE custodian** then transmits the completed M&TE Report to the ER Project M&TE database coordinator for data entry into the M&TE database.

6.2.12 The **M&TE database coordinator** shall transmit the M&TE Report to the Records Processing Facility (RPF) in accordance with QP-4.4, Records Transmittal to the Records Processing Facility.

6.3 Calibration of M&TE that is "Calibrated at Each Use"

6.3.1 The **M&TE custodian** places a label (see Attachment C) on or with the M&TE that lists, as a minimum, the ER M&TE identifier as listed on the M&TE Report and the statement "This instrument is calibrated at each use."

6.3.2 The **M&TE user** documents the calibration and use of M&TE that is "calibrated at each use" in accordance with QP-5.7, Notebook Documentation for Environmental Restoration Technical Activities.

6.4 Out-of-Calibration M&TE

6.4.1 The **M&TE custodian** and **M&TE users** ensure that any M&TE that are out of calibration are not used until they have been recalibrated. M&TE that are calibrated at a set frequency are considered to be out-of-calibration under the following conditions:

- if results are known to be in error;
- if the calibration due date has passed;
- if equipment software has been upgraded; or
- if any condition exists that could have changed the M&TE's calibration (e.g., if movement of the M&TE could cause it to be out of calibration, and it has been moved).

6.4.2 The **M&TE custodian** controls the use of the M&TE by placing a tag, label, or other suitable markings to indicate that it is out of calibration.

6.4.3 The **M&TE custodian** verifies that out-of-calibration M&TE are either calibrated in accordance with Section 6.2 or are removed from the ER Project in accordance with Section 4.5 of this QP.

6.4.4 If the M&TE accuracy was out of tolerance before calibration, could not be calibrated within the specified tolerance, or was lost, and was used to collect data governed by ER Project procedures since its last calibration, the **M&TE custodian** completes an M&TE Evaluation Report (Attachment B).

6.4.5 If the out-of-tolerance condition did not affect data, the **M&TE custodian** attaches the M&TE Evaluation Report to the M&TE Report.

6.4.6 If the out-of-tolerance affected data, the **M&TE custodian** initiates a Nonconformance Report in accordance with QP-3.4, Managing Nonconformances, Deficiencies and Corrective Actions, to document the evaluation disposition of the validity of results, and attaches the M&TE Evaluation Report to the M&TE Report.

6.4.7 The **M&TE custodian** transmits the M&TE Report to the RPF in accordance with QP-4.4, Records Transmittal to the Records Processing Facility.

6.4.8 The **M&TE custodian** ensures that M&TE that is consistently out of calibration is either repaired or replaced, and for lost M&TE removes it from the ER Project's M&TE control system in accordance with Section 6.5 of this QP.

6.5 Removing M&TE from the M&TE Database

6.5.1 The **M&TE custodian** ensures that the M&TE is calibrated before removing it from the M&TE database if they were used to collect data since their last calibration;

6.5.2 The **M&TE custodian** indicates in Section III of the M&TE Report that the M&TE was removed from service (and the date removed) and completes line 21;

6.5.3 The **M&TE custodian** transmits the M&TE Report to the M&TE database custodian for M&TE database entry; and,.

6.5.4 The **M&TE database coordinator** will transmit the M&TE Report to the RPF in accordance with QP-4.4, Records Transmittal to the Records Processing Facility.

6.6 Storage of M&TE

6.6.1 **The M&TE custodian** ensures that M&TE, when placed in storage, are appropriately stored, handled, and protected to maintain accuracy and to reduce the likelihood of damage or loss.

6.6.2 **The M&TE custodian** ensures that access to designated M&TE storage is adequately controlled.

Note: Methods may include locked cabinets, rooms, buildings, or other appropriate means.

6.7 Control of Consumable Standards

In order to track and assure control of consumable standards, the **M&TE custodian** documents the applicable information, as addressed in QP-5.7, Notebook Documentation for Environmental Restoration Technical Investigations, Attachment D.

6.8 Perform Lessons Learned

During the performance of work, **ER Project personnel** shall identify, document and submit lessons learned, as appropriate in accordance with QP-3.2, Lessons Learned, located at: http://erinternal.lanl.gov/home_links/Library_proc.htm.

7.0 RECORDS

The **M&TE database coordinator** transmits the following records, as applicable, to the RPF in accordance with QP-4.4, Records Transmittal to the Records Processing Facility.

7.1 M&TE Report

7.2 M&TE Evaluation Report

7.3 Electronic copies of the M&TE report and evaluation report

7.4 Information supplemental to the M&TE Report and M&TE Evaluation Report

8.0 TRAINING

8.1 ER Project personnel using this QP are trained by reading the procedure. The **user** shall ensure the training is documented in accordance with QP-2.2, Personnel Orientation and Training, and is entered in the ER Project Training Database located at http://erinternal.lanl.gov/Training/Training.asp.

8.2 The **supervisor** shall monitor the proper implementation of this procedure and ensure that relevant team members have completed all applicable training assignments in accordance with QP-2.2.

9.0 ATTACHMENTS

Attachment A: M&TE Report (1 page), located at http://erinternal.lanl.gov/Quality/forms.htm

Attachment B: M&TE Evaluation Report (1 page), located at http://erinternal.lanl.gov/Quality/user/forms.asp

Attachment C: M&TE Required Calibration Labels Examples (1 page)

Attachment D: M&TE Optional Calibration Labels Examples (1 page)

Using a token card, click here to record "self-study" training to this procedure.

If you do not possess a token card or encounter problems, contact the RRES-ECR training specialist.

M&TE Report

Section I. (M&TE Custodian completes)

1. M&TE identifier: _____ 2. Description: _____ 3. Location: _____

4. Capacity/range: _____ 5. Tolerance required: _____ 6. Calibration frequency: _____

7. Special handling, storage, maintenance, instructions: _____

8. Assigned custodian: _____
(print name)

9. A nationally recognized reference standard does not exist; the basis for calibration is as follows: _____

_____

10. The accuracy of the reference standard equals the required calibration tolerance, and the basis for the calibration is as follows: _____

_____

Note: M&TE Custodian signature only required when entering M&TE into Los Alamos ER Project M&TE database or for subsequent changes to the information in Section I.

11. M&TE Custodian: _____ _____ _____
Print name and title | Signature | Date

Section II. (Calibrator completes, or information is provided on separate, but comparable, attached documentation)

12. Calibration procedure/revision no.: _____ 13. Reference standard identifier: _____ 14. Reference standard description: _____

15. Reference standard accuracy: _____ 16. Accuracy before calibration: _____ 17. Accuracy after calibration: _____

18. ☐ M&TE within tolerance before calibration ☐ M&TE calibrated within the specified tolerance
☐ M&TE not within tolerance before calibration ☐ M&TE could not be calibrated within the specified tolerance

19. Calibrator: _____ _____ _____
Print name and title | Signature | Date

Section III. (M&TE Custodian completes)

20. Calibration status:

☐ M&TE calibration checked and within tolerance
☐ M&TE not used since last calibration
☐ M&TE's next calibration due date:
☐ M&TE removed from the ER Project this date:
☐ M&TE not within tolerance before calibration—not used since last valid calibration
☐ M&TE not within tolerance required before calibration—M&TE evaluation RPT attached

21. M&TE Custodian: _____ _____ _____
Print name and title | Signature | Date

QP-5.2

Los Alamos
Environmental Restoration Project

M&TE Evaluation Report

Section I.

M&TE Identifier:

M&TE Description:

On the M&TE identified above

- ☐ was out of tolerance.
- ☐ could not be calibrated.
- ☐ could not be located.

Was the device used to collect data?

- ☐ No, Complete Section III of this form.
- ☐ Yes, determine if the data collected were affected by the identified condition and document the results in Section II of this form.

Section II.

Evaluation:

a) Identify the data collected:

b) Identify the processes monitored:

c) Identify the notebooks reviewed:

d) Conclusion: The validity of results obtained with the M&TE or Standard and the acceptability of data collected since the last calibration have been evaluated as required, and is documented as follows:

- ☐ data are acceptable (complete Section III, below).
- ☐ data are unacceptable (initiate nonconformance report and complete Section III, below).

Nonconformance report number: _____

Section III.

The impact of the identified condition has been evaluated.

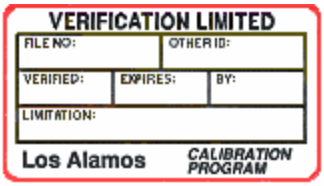
Print name and title	Signature	Date

QP-5.2	Los Alamos Environmental Restoration Project

M&TE Required Calibration Labels

Certified (blue border). The item has been calibrated by ESA-MT and meets all applicable specifications (after adjustments, if any).

Certification Limited (red border). The item has been calibrated by ESA-MT but does not meet all applicable specifications (after adjustments, if any); or, the item has been calibrated by ESA-MT over a limited subset of its available functions, ranges, or attributes.

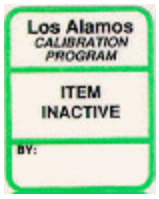


Verification Limited (red border). The item has been calibrated by the user or by a calibrator other than ESA-MT but does not meet all applicable specifications (after adjustments, if any); or, the item has been calibrated by the user or by a calibrator other than ESA-MT over a limited subset of its available functions, ranges, or attributes.

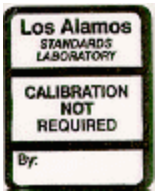
Verified (tan border). The item has been calibrated by the user or by a calibrator other than ESA-MT and meets all applicable specifications (after adjustments, if any).

M&TE Optional Calibration Labels

Verify Before Use (orange border). The item must be calibrated by the user before quality-or safety-affecting activities are conducted.



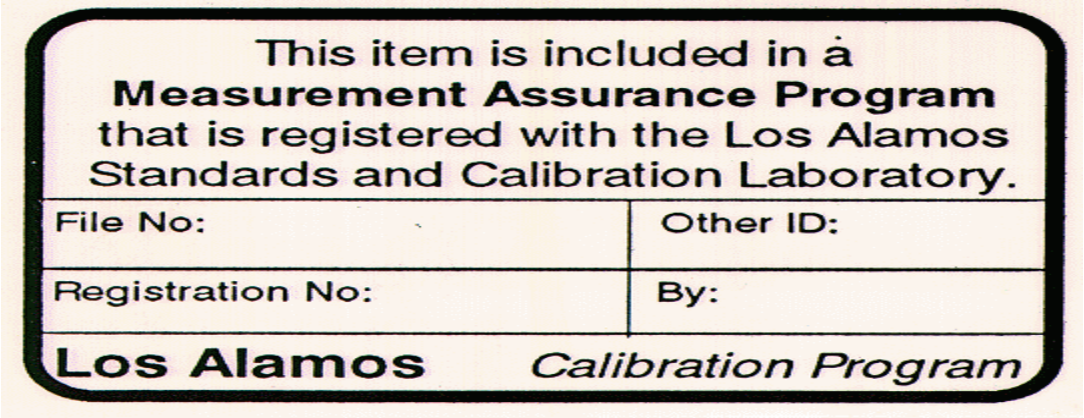
Item Inactive (green border). The item is intended for measurements but is not in use at the present time.



Calibration Not Required (black border). The item is not relied on for measurement data. When necessary, output parameters of these items are monitored by calibrated equipment.

Calibration Expired (black on red). The item has been previously calibrated and has exceeded its expiration

Calibration Void If Seal Is Broken (black on silver). The item has externally accessible adjustments that, if disturbed, will invalidate the calibration. The label is attached so that any attempt to adjust the item will break the



Measurement Assurance Program (black border). The item is included in a formal measurement assurance program (a quality control program that calibrates an entire measurement system).